

REMARKS

As an initial matter, Applicants' attorney acknowledges election of Claims 15, 16, 18 and 20 for examination in the present application in accordance with the restriction requirement of August 27, 2007. Claims 1-14 have been cancelled, and Claims 17 and 19 have been withdrawn from consideration. Applicants' attorney notes with appreciation that the Examiner has withdrawn the earlier requirement to elect a specific polymer and specific bioactive agent for examination. By the foregoing amendments, independent Claim 15 and dependent Claim 16 have been amended, and new dependent Claims 21-31 have been added.

Turning to the Office Action, the Examiner has rejected Claims 15 and 20 for obviousness under 35 U.S.C. § 103(a) over Sukhishvili et al. (Journal of the American Chemical Society 2000 122:9550-9551) ("the Sukhishvili Paper"), in view of Decher et al. (Macromolecules 1993 26:5396-5399) ("the Decher Paper"). Applicants respectfully traverse this rejection.

In the method of amended Claim 15, a multilayer film having alternating layers of a polymer and a macromolecule bonded to each other at least through electrostatic interactions is formed at a pH at which the film has a charge balance of approximately one. The pH of the film is adjusted so as to create an excess charge of the film without destroying the film, thereby selectively releasing a controlled quantity of the macromolecule so as to restore the charge balance to approximately one. The quantity of the macromolecule that is released is substantially proportional to the excess charge.

In contrast to amended Claim 15, the Sukhishvili Paper teaches the formation of a multi-layer film having alternating layers of different polymers bonded to each other through hydrogen-bond interactions (page 9550, col. 1, par. 1, lines 7-11 and

par. 2, lines 1-4). It does not address the formation or desirability of forming electrostatic bonds among the layers of the film. Adjusting the pH so as to create an excess charge of the hydrogen-bonded film results in the destruction of the film and its dissolution (page 9550, col. 2, par. 3). The destruction of the film occurs suddenly and releases all of the chemical components of the film at once (page 9550, col. 2, par. 3; and Fig. 2). Contrary to amended Claim 15, the quantity that is released is not controlled and is not proportional to the excess charge, since the entire quantity is released.

The Examiner states that the Sukhishvili Paper teaches that the layers of a layered polymer film can be selectively removed. As discussed above, the Sukhishvili Paper teaches the destruction of multi-layered films. It does not teach the removal of single layers of such films. Further, Applicants' attorney notes that the removal of single layers from a multi-layer film is not an element of amended Claim 15.

The Decher Paper teaches that multi-layer films can be formed by alternately depositing layers of anionic and cationic polyelectrolytes, and that DNA can be used as a polyanion in place of an anionic polyelectrolyte. However, the Decher Paper does not teach that macromolecules, such as DNA, may be released from such multi-layer films in response to the creation of excess charges of the film, as is recited in amended Claim 15. Thus, combining the teachings of the Decher Paper with those of the Sukhishvili paper would not render amended Claim 15 obvious.

The Examiner has also rejected Claims 15, 16 and 18 for obviousness under 35 U.S.C. § 103(a) over the aforementioned combination of the Sukhishvili Paper and the Decher Paper, in further view of U.S. Patent Publication No. 2003/0215626 to Hiller et al. ("the Hiller Publication"). Applicants respectfully traverse this rejection. The combination of the Sukhishvili Paper and the Decher Paper has been discussed above.

The Hiller Publication teaches the reversible formation of nanopores in multi-layer polyelectrolyte films by adjusting an environmental parameter, such as pH adjustment. Contrary to amended step (d) of Claim 15, the Hiller Publication does not address the creation of excess charges in such a film by pH adjustment or that a selective release of a controlled quantity of molecules from the film would occur in response to the creation of such excess charges. The method of amended Claim 15 would not be obvious from the teachings of the Hiller Publication because the release of molecules from a multi-layer film in response to the creation of an excess charge involves different chemical principles than those involved in changing the conformation of the polymers in such a film (i.e., the formation of nanopores). Thus, for the aforementioned reasons, combining the teachings of the Hiller Publication with the combination of the Sukhishvili Paper and the Decher Paper would not render amended Claim 15 obvious.

Applicants' attorney notes that the Hiller publication mentions a possibility that the size of the nanopores in a multi-layer film might be adjusted so that molecules associated with the film would be released through the nanopores. Such a release mechanism, if practical, would be completely different from the release mechanism recited in amended Claim 15 (i.e., the selective release of a controlled quantity of a macromolecule from a multi-layer film in response to an excess charge of the film), and would not render amended Claim 15 obvious over the aforementioned combination of the Sukhishvili Paper, the Decher Paper and the Hiller Publication.

For the reasons discussed above, Applicants believe that amended Claim 15 is not obvious over either combination of references cited by the Examiner. Therefore, Applicants' attorney respectfully urges the Examiner to withdraw her rejection of Claim 15, and allow the amended claim. Since Claims 16, 18 and 20, as well as new

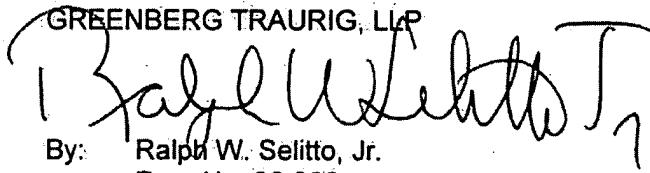
U.S. Patent Application No. 10/624,993
Response to Office Action dated February 22, 2008
Page 9 of 9

Claims 21-31, depend from amended Claim 15, Applicants' attorney requests that these claims also be allowed. Further, since non-elected Claims 17 and 19 depend from amended Claim 15, Applicants' attorney urges that the withdrawal of these claims be reversed, and the claims allowed.

The Examiner is authorized to charge a fee of \$230 to Deposit Account 501561 for the accompanying Extension Petition to extend the period for response by two months, to and including July 22, 2008. Applicants' attorney believes that no other fees are due as a result of this Amendment or for the Extension Petition. If any such fees are due, including any petition fees or fees for extending the time for response, the Examiner is authorized to charge any deficiency, and/or credit any overpayment to Deposit Account No. 501561.

Respectfully submitted,

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